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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/888,757 | 06/25/2001 | John E. Ahern | B0410/7282D1 | 2885 |
| 22832 | 7590 | 10/19/2004 | EXAMINER | |
| KIRKPATRICK & LOCKHART LLP | | | WILLIAMS, CATHERINE SERKE | |
| 75 STATE STREET | | | ART UNIT | |
| BOSTON, MA 02109-1808 | | | PAPER NUMBER | |
| | | | 3763 | |

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,757

Applicant(s)

AHERN ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22314
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3763

DETAILED ACTION

Election/Restrictions

The requirement for the election of species in the Office Action dated 12/22/03 has been withdrawn in light of Applicant's remarks dated 7/28/04.

Information Disclosure Statement

The two PTO-1449(s) have been entered into the application and reviewed. However, some of the references are contained within the parent application (08/993,586). This file has been ordered from the repository and the references not yet reviewed will be initialed on the next correspondence when the parent file application has been received.

Claim Rejections - 35 USC § 112

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has failed to describe the "means for receiving at least one pellet" in the specification. One skilled in the art is not able to determine functional equivalents from the specification for the means; therefore, the claim is indefinite and not distinctly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3763

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-21, 23-26, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (US Pat# 4,588,395). Lemelson discloses an elongate flexible body (31), a delivery chamber/means for receiving (32) with a space and a port, and an actuator (17). The device also includes a control mechanism (20) and a plunger (36). The device is disclosed for use in arteries; therefore, its diameter is dimensioned small enough to traverse the vessels leading from the heart of a patient thereby making it small enough to enter the larger atrium and/or ventricles of the heart. See 2:35. The delivery chamber, as shown in figures 1,2 and 3 is substantially a cylindrical housing which is dimensioned to store a plurality of minispheres. Even though only one implant is shown within the delivery chamber, the length of the chamber clearly shows that the chamber is capable of housing multiple smaller implants in axial alignment. The implant may be “implanted into the tissue adjacent said head when the latter is disposed at a given location in a body duct, such as an artery, the intestine, throat or other body duct”. See Detailed Description paragraph 1. A pointed distal end (34) is shown in figure 1 that has a beveled construction that would facilitate penetrating tissue with enough force. The distal end of the device in figure 2 has an arcuate shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3763

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Matsuno et al (US Pat# 5,342,394). Lemelson meets the claim limitations as described above and additionally discloses that the invention (catheter) is inserted into an animal or human body and “manipulated so as to provide the head end of the device at a fixed location within the body”. Yet, Lemelson fails to include a steering mechanism.

However, Matsuno discloses a catheter that includes a flexible body (1) with an actuator (14) and also includes a steering mechanism (31). See Figure 9.

At the time of the invention, it would have been obvious to incorporate the steering mechanism of Matsuno into the invention of Lemelson. The devices are analogous to each other and also the claimed invention; therefore, a combination is proper. Additionally, Lemelson makes reference to “manipulating” the device to a fixed location in the body. It is well known in the vascular catheter art that steering mechanisms ease the manipulating of tubular flexible bodies (catheters) to fixed locations within a patient’s body. Hence, the motivation for making the combination would have been in order to enhance the manipulating ability of the device of Lemelson.

Claims 27-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Leschinsky et al (US Pat# 5,873,499). Lemelson meets the claim limitations as described above but fails to include a ratchet assembly, a threaded plunger or a lever-action handle.

Art Unit: 3763

However, Leschinsky discloses a dispensing gun that includes a plunger (92) that may be threaded, notched (ratchet) or grooved (ratchet). The gun also includes a handle (62) that has a trigger (104) and a pawl (108).

At the time of the invention, it would have been obvious to substitute the threaded plunger of Leschinsky for the actuation assembly and plunger of Lemelson; and the handle, trigger and pawl of Leschinsky for the control mechanism of Lemelson. Both prior art references are analogous in the implant dispenser art and are also analogous with the claimed invention; therefore, a combination is proper. Additionally, it is well known in the art that trigger mechanisms with threaded or ratcheted dispenser mechanisms are more stable than hand actuated dispensing mechanism, such as the one by Lemelson. Therefore, the motivation for the combination would have been in order to enhance the control of the dispensing of the implant of Lemelson thereby increasing the safety of the device to the patient.

Response to Arguments

In response to applicant's argument that the prior art fails to specifically disclose that the device implants the material within a tissue wall, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Art Unit: 3763

In this case, the actuator, even though not specifically disclosed, is "capable of driving the therapeutic agent through the port whereby the therapeutic agent is implanted within a tissue wall". It is considered "capable" because with enough force any object can pierce a tissue. Additionally, see above for language from the specification of Lemelson that teaches that the implant may be implanted within tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams *CSW*
October 8, 2004



NICHOLAS D. LUCCHESI
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